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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,831

11/24/2003

Richard A. Berg

C94-018-D2

2955

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04/21/2006

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/720,831

Applicant(s)

BERG ET AL.

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2003 and 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1652

Applicant's election without traverse of Group I, claims 1-9 and 14-16 in the reply filed on 2/16/06 is acknowledged.

Claims 10-13 and 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/16/06.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,653,450. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the instant patent make obvious the instant claims. The issued claims are drawn to a molecule comprising a collagen peptide attached to a C-terminal propeptide at one end by a cleavage site and attached to a second propeptide by another cleavage

Art Unit: 1652

site. The instant claims are drawn to a molecule comprising the collagen peptide attached by a cleavage site to the C-terminal propeptide only. This reads on the patented claims since the instant claims comprise the collagen, the cleavage site and the propeptide and can include anything else.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-9 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu, et al. (AF), Prockop, et al. (AG) and Olsen, et al. (AH) in view of Carter, et al. (AD) and the doctrine of *res judicata*. The identical claims were rejected over the instant references in the parent application, appealed to the Board of Patent Appeals and Interferences, a request for rehearing was requested and denied and finally was appealed to the U.S. Court Of Appeals For The Federal Circuit. The rejection of the instant claims over the instant references was upheld at each level of appeal.

Chu, et al. and Prockop, et al. each teach the human pro $\alpha$ 1(I) procollagen and the N and C-terminal propeptides (see Fig. 3 in each). Olsen, et al. teach the C-terminal propeptide of type I procollagen. Carter, et al. teach that a gene can be fused so as to produce fusion proteins and that these fusion proteins can be specifically cleaved using various chemical and enzymatic means (see Table I). It would have been obvious to one of ordinary skill in the art to make a fusion protein that consisted of collagen and either the

Art Unit: 1652

N or C-terminal propeptide, as taught in the primary references, using the methods taught in Carter, et al. As stated in the specification on page 8, lines 17-33, the nucleic acid sequences of the collagens and site-specific cleavage sites are readily available. Whether or not a non-natural amino acid was used and which specific cleavage site and agent was used would have been obvious and well within the skill level of one of ordinary skill in the art, absent unexpected results.

The motivation would have been to be to purify the collagen with an affinity handle, as taught by Carter, et al. in the first paragraph. For instance, an antibody could be made to a particular procollagen, the construct of the instant claims could be put on an affinity column containing this antibody bound to a solid matrix, the contaminating proteins washed out and then the site-specific cleavage means could be employed to cleave the collagen molecule, thereby facilitating purification. This same procedure could also have been done batch-wise, not using a column. Another possible use for the construct of the instant claims be to facilitate purification not using affinity. Collagen will typically precipitate out of solution when the procollagen is removed. One could make the claimed construct having one or two procollagens attached (for instance by genetic engineering) and have it produced by a host cell. Then the construct could be purified in solution and finally as a last step the procollagens could be cleaved off, giving purified collagen as a precipitate.

The 11 references crossed out on the PTO-1449 were not cited in the parent application (08/270,774) as stated by the applicants in the IDS filed 11/24/03.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
April 17, 2006